



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1630]

Draft Guidance for Industry on Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease.” This draft guidance provides a statement of qualification for the Exacerbations of Chronic Pulmonary Disease Tool (EXACT) patient-reported outcome instrument and summarizes the concept of interest and context of use (COU) for which the tool is qualified through the Center for Drug Evaluation and Research’s (CDER’s) drug development tool (DDT) qualification program. Qualification of the EXACT represents a conclusion that, within the stated COU, the instrument can be relied on to have a specific interpretation and application in drug development and regulatory review. This draft guidance is an attachment to the guidance for industry entitled “Qualification Process for Drug Development Tools.”

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elektra J. Papadopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6429, Silver Spring, MD 20993-0002, 301-796-0900.

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease.”

In March 2006, FDA issued the “Critical Path Opportunities Report and List”, in which FDA described six key areas along the critical path to improved therapies and listed specific

opportunities for advancement within these topic areas. The report noted that a new product development toolkit containing new scientific and technical methods was needed to improve the efficiency of drug development.

Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers and clinical outcome assessments (COAs). CDER has developed a formal process, the DDT qualification process, to work with developers of these tools to guide them as they refine the tools and rigorously evaluate them for use in the regulatory context. Once qualified, DDTs will be publicly available for use in any drug development program for the qualified COU. COA DDTs are developed and reviewed using this process when they are intended ultimately for use as primary or secondary endpoints in clinical trials designed to provide substantial evidence of treatment benefit. Upon qualification by CDER, a qualification statement is provided describing the concept of interest and COU for which the tool is qualified. This draft guidance describes the qualification statement for the EXACT, a COA DDT.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the qualification of the EXACT COA DDT. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: January 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.